5. Summary of Safety and Effectiveness

5.1 Date of application: 07/07/2003

5.2 Applicant's name and address: Remco Italia spa
Via Rivoltana Nuova 53
20060 San Pedrino di Vignate
(Milan) ITALY

5.3 Contact person: Mr. Luigi Bucchi
Tel: +39029505181
Fax: +39029566013
E-mail: L.bucchi@cardioline.it

5.4 Device Trade Name
Click Holter

5.5 Device Common Name
Electrocardiograph, Ambulatory (without analysis)

5.6 Device Classification Name
CFR 870.2800 Medical magnetic tape recorder
Class II MWJ

5.7 Predicate Device
The legally marketed device to which equivalence is being claimed is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
Braemar Inc.	Braemar Inc.	DXP1000 Holter recorder	K993618

Table 5.7.1 reports a technical comparison between Click Holter device and DXP1000 Predicate device.

Summary of Safety and Effectiveness (con't)

Table 5.7.1

Parameter	Click Holter	DXP1000
Storage capacity	Up to 48 hours	Up to 48 hours
Memory type	Flash (non-volatile)	Flash (non-volatile)
Memory portability	Non removable	Non removable
On-board ECG analysis	No	No
Liquid Cristal Display (LCD)	No	Yes
Led indicators	Yes	No
Data Transfer method	USB port	USB port
Pace maker detection & reporting	Yes	Yes
Battery	Two AA	Two AA
Size	11 x 8 x 1.5 cm	11 x 7 x 2 cm
Weight	149 gr	141 gr

5.8 Device description

Click Holter is a personal three channels Ambulatory ECG recorder characterized by the following features:

- Up to 48 hours continuous ECG recording on three independent leads
- USB port for fast download of recorded data
- Possibility to store patient data in the recorder via USB port

5.9 Intended use

The device is intended for patients requiring ECG Ambulatory (Holter) monitoring up to 48 hours.

5.10 Comparison of technological characteristics

Click Holter ECG Ambulatory recorder is based on technological characteristics similar to the predicate device DXP 1000.

5.11 Non clinical tests used for Substantial Equivalence Determination

Full safety tests according to IEC 601-1 / EN60601-1 Standard and performances tests according to IEC 601-2 47 / EN 601-2-47 and AAMI EC 38 1994 Standard have been performed on Click Holter.

The equipment have been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard.

Summary of Safety and Effectiveness (con't)

No adverse working conditions have been claimed and filed up to date.

An identical version of the device is CE marked according to 93/42/CEE Medical Device Directive.

5.12 Conclusions

Based on the above, Remco Italia believes that Click Holter Ambulatory ECG recorder is substantially equivalent to Predicate device DXP 1000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2003

REMCO ITALIA S.p.A.
c/o Mr. Ligui Bucchi
Strada Rivoltana Nuova, 53
20060 San Pedrino di Vignate
Milan, Italy 20060

Re: K032276
Trade Name: Click Holter
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: July 7, 2003
Received: July 23, 2003

Dear Mr. Bucchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032276

Device Name: CLICK Holter Three-Channel Ambulatory ECG Recorder

Indications For Use:

The Click Holter recorder is intended for patients requiring ambulatory (Holter) monitoring from 1 to 48 hours. Such monitoring is most frequently used for the indications below:

a) Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
b) Evaluation of ECG documenting therapeutic interventions in individual patients or group of patients.
c) Evaluation of patient's ST segment alterations.
d) Patient follow up after M.I. or cardiac surgery.
e) Clinical and epidemiological studies
f) Pace maker evaluation
g) Time or Frequency domain heart rate variability analysis
h) Qt interval analysis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032276